Syphilis AccuSet™ Performance Panel

0820-0214 / Batch #10187583

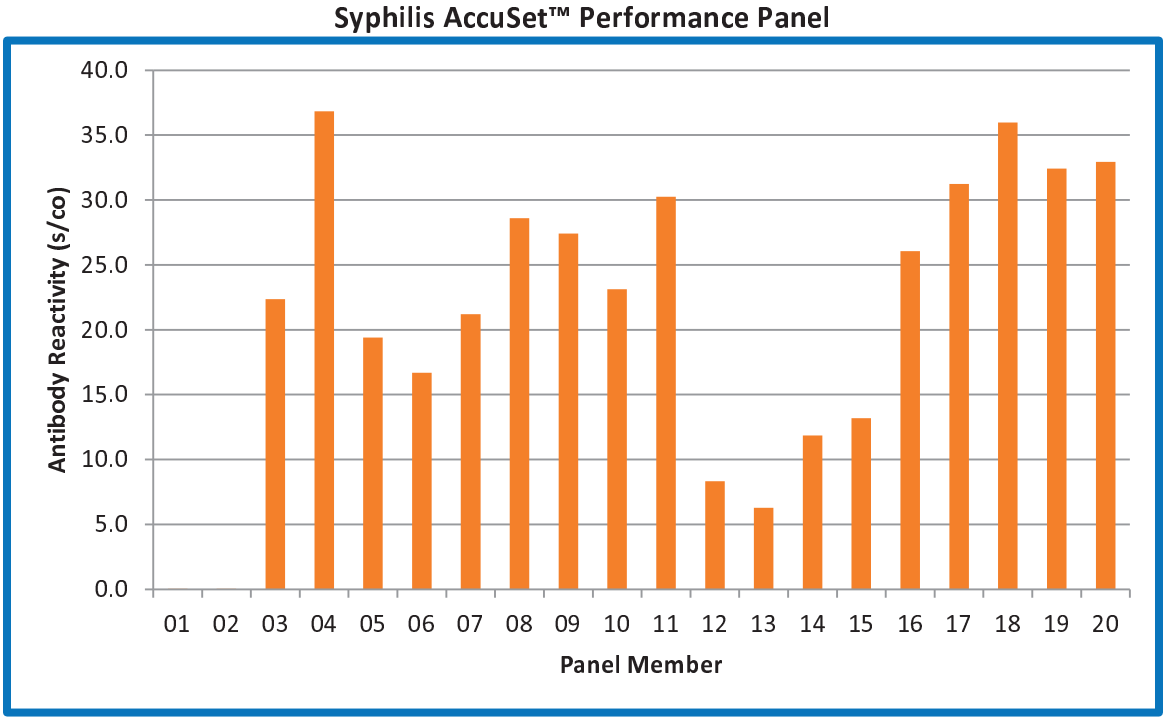
OVERVIEW

Syphilis AccuSet™ Performance Panel (0820-0214) is a 20-member panel of undiluted, naturally occurring plasma samples (1 vial per member, 1.2mL per vial). Panel members represent bleeds from multiple individuals positive for Syphilis. Each sample represents a single collection event. No preservatives were added.

Test results from commercially-available non-treponemal and treponemal assays are included for the characterization of each panel member. This panel of human plasma samples demonstrates reactivity ranging from negative to high positive for Syphilis antibodies. Two members are included as non-reactive to all non-treponemal and treponemal test methods performed.

For Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly.

CAUTION: Potentially infectious materials. Follow Universal Precautions. The units that make up this panel were tested and found negative for anti-HIV 1/2, HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens.



This graph demonstrates antibody reactivity for each panel member on the Abbott ARCHITECT Syphilis TP assay. Data are provided for informational purposes only.

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Panel Member Information

Panel Member	SeraCare Batch #	SeraCare Donor ID #	Gender	Age	Country of Origin	Bleed date
01	9252292	NA	NA	NA	NA	NA
02	9252293	NA	NA	NA	NA	NA
03	9222570	NA	NA	NA	NA	NA
04	9244706	NA	NA	NA	ZA	NA
05	9231132	BD106706	NA	45	NA	06/03/2008
06	9231151	BD106747	NA	NA	NA	05/19/2008
07	9231403	BD106790	NA	32	US	05/23/2008
08	BM201379	BD100687	NA	NA	NA	01/31/2005
09	BM201380	BD100687	NA	NA	NA	01/26/2005
10	BM206251	BD102686	NA	NA	NA	04/20/2006
11	BM216451	BD102985	NA	NA	NA	05/29/2006
12	BM216818	BD103211	NA	NA	NA	11/03/2006
13	BM216855	BD103220	NA	NA	NA	10/03/2006
14	9168179	NA	NA	NA	NA	NA
15	9203127	BD111324	NA	NA	NA	08/30/2006
16	10112119	BD240189	Female	NA	US	01/10/2015
17	10112122	BD240192	Male	NA	US	09/12/2014
18	10118407	BD245060	Male	28	NA	05/09/2014
19	10118411	BD245064	Male	31	NA	07/29/2013
20	9225825	NA	NA	NA	NA	NA

NA = Not available

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Non-Treponemal Assays – Rapid Plasma Reagin (RPR)[1]

Panel Member	ASI™ RPR Card Test	BD Macro-Vue™ RPR Card Test
01	NEG	NEG
02	NEG	NEG
03	**POS**	**POS**
04	**POS**	**POS**
05	**POS**	**POS**
06	**POS**	**POS**
07	**POS**	NEG
08	**POS**	**POS**
09	**POS**	**POS**
10	**POS**	**POS**
11	**POS**	**POS**
12	**POS**	NEG
13	**POS**	NEG
14	**POS**	NEG
15	NEG	NEG
16	**POS**	**POS**
17	**POS**	**POS**
18	**POS**	**POS**
19	**POS**	**POS**
20	**POS**	**POS**
Test Date	14Apr2016	13Apr2016
Test Site	RL	SC
Kit Part Code	NA	274449
Kit Lot No.	NA	5009811
Kit Exp. Date	NA	31Jan2017
Kit Regulatory Status	IVD	IVD

[1] Results are generated from duplicate testing. Results in bold red are considered positive/reactive.
POS = Positive; NEG = Negative
RL = Reference Lab; SC = SeraCare Life Sciences; NA = Not Available; IVD = In Vitro Diagnostic

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Treponemal Assays – Total Antibodies[1]

Panel Member	Abbott ARCHITECT Syphilis TP (s/co)[2]	Beckman Coulter PK TP System	DiaSorin Liaison® Treponema Screen (INDEX)	Immucor TPHA Screen
01	0.03	NEG	<0.1	NR
02	0.03	NEG	<0.1	NR
03	**22.4**	**POS**	**>70.0**	NR
04	**36.8**	**POS**	**46.3**	**R**
05	**19.4**	**POS**	**>70.00**	**R**
06	**16.7**	**POS**	**>70.0, 62.4**[3]	NR
07	**21.2**	**POS**	**>70.0**	**R**
08	**28.6**	**POS**	**>70.0**	**R**, NR[4]
09	**27.4**	**POS**	**>70.0**	**R**
10	**23.1**	**POS**	**>70.0**	**R**, NR[4]
11	**30.2**	**POS**	**>70.0**	**R**
12	**8.3**	**POS**	**>70.0**	NR
13	**6.3**	**POS**	**>70.0**	**R**, NR[4]
14	**11.9**	**POS**	**65.4**	NR
15	**13.2**	**POS**	**31.2**	NR
16	**26.1**	**POS**	**68.8**	**R**
17	**31.2**	**POS**	**64.9**	**R**
18	**36.0**	**POS**	**49.8**	**R**
19	**32.4**	**POS**	**47.8**	**R**
20	**32.9**	**POS**	**44.9**	**R**
Test Date	20Apr2016	15Apr2016	15Apr2016	14Apr2016
Test Site	RL	RL	RL	RL
Kit Part Code	NA	NA	NA	NA
Kit Lot No.	60673LI00	UR00082	113041X	NA
Kit Exp. Date	16Dec2016	31Oct2016	13Sep2016	NA
Kit Regulatory Status	CE	IVD	IVD	IVD

[1] Results are reported as a mean result of duplicate testing. Results in bold red are considered positive/reactive.
[2] Immunoassay results are expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered positive.
[3] During the course of duplicate testing, one replicate tested on-scale at 62.4, the second replicate was off-scale at >70.0.
[4] During the course of duplicate testing, one replicate tested as reactive, the second replicate was non-reactive.
POS = Positive; NEG = Negative; R = Reactive; NR = Non-Reactive
RL = Reference Lab; SC = SeraCare Life Sciences; NA = Not Available; IVD = In Vitro Diagnostic; CE = Conformité Européenne or CE Marking

DATA SHEET

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Treponemal Assays – IgG / IgM[1]

Panel Member	Bio-Rad BioPlex® 2200 Syphilis IgG	Calbiotech EIA Syphilis IgM (s/co)[2]
01	NEG	0.4
02	NEG	0.7
03	**POS**	**4.1**
04	**POS**	**4.7**
05	**POS**	0.6
06	**POS**	0.8
07	**POS**	0.6
08	**POS**	**2.0**
09	**POS**	**1.8**
10	**POS**	**2.2**
11	**POS**	0.7
12	**POS**	**2.4**
13	**POS**	0.5
14	**POS**	**1.6**
15	**POS**	**1.2**
16	**POS**	**3.5**
17	**POS**	**4.1**
18	**POS**	**2.4**
19	**POS**	**>5.8**
20	**POS**	**>5.8**
Test Date	16Apr2016	29Apr2016
Test Site	RL	SC
Kit Part Code	NA	TP089M
Kit Lot No.	NA	TPM4793
Kit Exp. Date	NA	28Feb2017
Kit Regulatory Status	IVD	IVD

[1] Results are reported as a mean of duplicate testing. Results in bold red are considered positive/reactive.
[2] Immunoassay results are expressed as signal to cutoff ratios (s/co). Ratios ≥1.0 are considered positive.
POS = Positive; NEG = Negative
RL = Reference Lab; SC = SeraCare Life Sciences; NA = Not Available; IVD = In Vitro Diagnostic

The package insert for this panel can be found at www.seracare.com

A printed copy of the package insert or data sheet may be requested by email at info@seracare.com, or by phone at 508.244.6400